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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/288,336 08/10/94 LUCIW

P 0035.011

EXAMINER

WOODWARD, M

18N1/0410

ART UNIT

PAPER NUMBER

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INTELLECTUAL PROPERTY R440
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1813

DATE MAILED:

04/10/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on 8/10/94 This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892.
2. Notice of Draftsman's Patent Drawing Review, PTO-948.
3. Notice of Art Cited by Applicant, PTO-1449.
4. Notice of Informal Patent Application, PTO-152.
5. Information on How to Effect Drawing Changes, PTO-1474.
6.

Part II SUMMARY OF ACTION

1. Claims 26 is pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. Claims 1-25 & 27-59 have been cancelled.

3. Claims _____ are allowed.

4. Claims 26 is rejected.

5. Claims _____ are objected to.

6. Claims _____ are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been approved by the examiner; disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed _____, has been approved; disapproved (see explanation).

12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____.

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other

The disclosure is objected to because of the following informalities:

Section 8. of the specification lacks dates of deposit and ATCC numbers for several of the recited strains. Applicant is referred to 37 C.F.R. §1.801-1.808 for guidance in perfecting the deposits.

5 Claim 26 is the sole pending claim, claims 1-25 and 27-69 having been cancelled in Paper No. 2 (August 10, 1994).

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, 15 as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

The specification does not set forth sufficient guidance to permit one to make the expression products within the scope of the claimed invention which would function for any of the disclosed utilities in the specification, e.g. 20 immunoassays or vaccines.

In order for the specification to be enabling for fragments of the viral proteins it is necessary that sufficient guidance be presented as to the reactivity of the fragments or their ability to induce an immune response. However, in this respect the specification is silent and does not suggest which amino acid

sequences of the viral genome are important to immunogenicity and antigenicity.

Currently, the claim encompasses all possible expression products and even if applicants could demonstrate that the art was aware of specific regions which could function in one of the disclosed utilities the specification would still not be enabling because there are still significant regions of the genome whose antigenicity and immunogenicity are unknown.

There are no currently available methods which permit one to reliably predict what amino acid sequences in a given protein will give rise to antibodies which are specific for native antigens and which also exhibit no cross-reactivity with related antigens. This topic has been reviewed recently by Stern (1991) wherein it is set forth that the rate of success in predicting epitopes is only about 50% (page 168, center column) which indicates that it until the experiment is done one cannot reasonably predict whether or not a sequence will function as an epitope of a larger polypeptide.

In addition, the absence of any functional language in claim 26 fails to provide guidance as to how to use the recited peptides.

Claim 26 is rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Because the specifications of the parent applications to which applicants

claim priority under the provisions of 35 U.S.C. §120 fail to meet the provisions of 35 U.S.C. §112, first paragraph the instant claim is accorded the filing date of the instant application, August 10, 1994.

5 The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

10 A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
15 (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 26 is rejected under 35 U.S.C. § 102(b or e) as being clearly anticipated by Haseltine et al. (US Patent 4,981,790).

20 Haseltine et al. discloses and claims vectors which express a portion of the *tat* gene of HIV.

The rejection is made under either the provisions of 35 U.S.C. §102 (b) or (e) so as to expedite prosecution.

25 The rejection under 35 U.S.C. §102(b) would be withdrawn upon a demonstration that the specification of SN 07/931,191 was enabling for the instantly claimed invention.

The rejection under the provisions of 35 U.S.C. §102(e) cannot be overcome by the filing of a Declaration under 37 C.F.R. §1.131 because the Haseltine patent claims a sub-genus of the instantly claimed invention.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

5 A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be
10 negated by the manner in which the invention was made.

15 Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

20 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or
25 (g) prior art under 35 U.S.C. § 103.

30 Claim 26 is rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Kaufman (US Patent 4,740,461) and Montagnier et al. (US Patent 4,708,818) in view of the level of skill in the art as represented by Reitz et al. (1981), Seiki et al. (1983) and Copeland et al. (1983).

30 Claim 26 is directed to a method of expressing portions of the HIV genome in mammalian cells such that the entire viral genome is not relied on.

There was motivation in the art at the time the invention was made to make such vectors as they would obviate the need for working with virally infected cells and the attendant risk of infection.

Kaufman teaches expression vectors for the production of mammalian proteins in culture mammalian cells. Kaufman suggests that virtually any coding sequence from a protein normally expressed in mammalian cells would be expected to function in his vectors, see column 4 for a list of exemplary 5 proteins.

Kaufman does not disclose the coding sequence for any HIV gene or portion thereof.

Montagnier et al. discloses that p25 is a viral protein of HIV, its use in immunoassays for the detection of antibodies in the sera of patients infected with 10 HIV, and suggests purification of p25 column 5, lines 42-51, as well as a protocol for isolating the virus.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to obtain the coding sequence for p25 and insert it into the vector of Kaufman with the reasonable expectation of producing a 15 polypeptide which would exhibit the activity of p25 and would have been motivated to do so in order to avoid the problems of working with live virus.

Obtaining the coding sequence for p25 would have involved routine experimentation given the level of skill in the art. From the teachings of Reitz et al. it is clear that the ordinary artisan possessed the requisite skill to obtain 20 cDNA clones which would span the genome of HIV. It is equally clear from Seiki et al. that the worker of ordinary skill would have been able to obtain the sequence of the genome of HIV from the cDNA clones and to determine the open reading frames of the virus. In addition, the teachings of Copeland et al. (1983) indicate that the worker of ordinary skill in the art had available the 25 means to determine the amino acid sequence of retroviral proteins. Given the sequence of p25 obtained from protein sequencing techniques the person of

ordinary skill in the art would have then determined which sequence elements of the viral cDNA corresponded to it and would have then proceeded to insert such cDNA elements into the expression vector of Kaufman.

5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Woodward whose telephone number is (703) 308-3890.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

10 Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

The CM1 Fax Center number is (703) 305-3014.

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MICHAEL P. WOODWARD
PRIMARY EXAMINER
GROUP 1800

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April 7, 1995